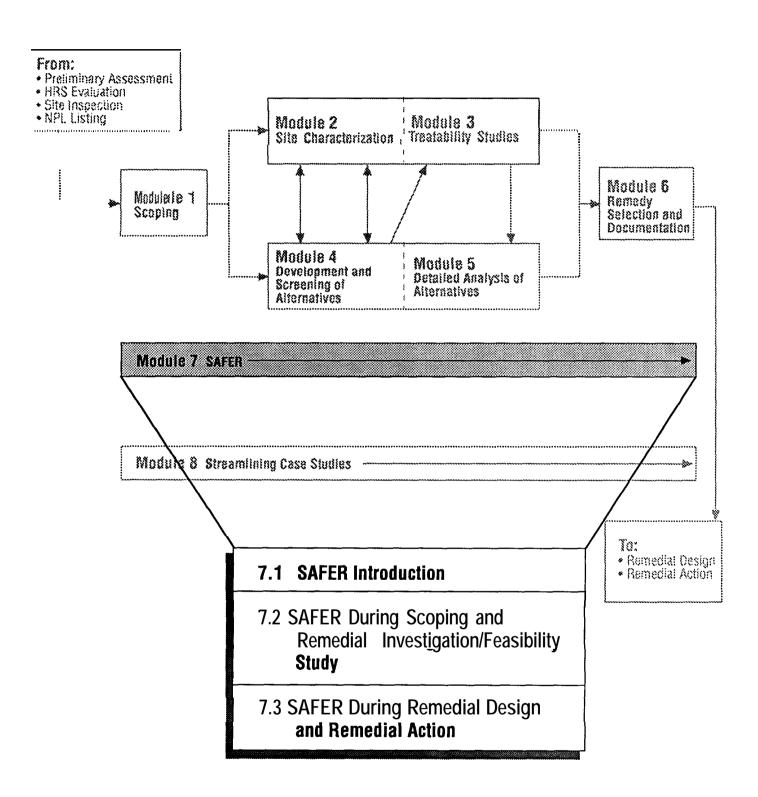
Module 7 **Streamlined Approach For Environmental Restoration**

Contents

		Page
7.1	SAFER Introduction	7-7
7.2	SAFER During Scoping and Remedial Investigation/Feasibility Study	7-21
7.3	SAFER During Remedial Design and Remedial Action	7-39



Module 7 Streamlined Approach For Environmental Restoration

Background

The Department of Energy (DOE) developed the Streamlined Approach For Environmental Restoration (SAFER) as a methodology tailored to the challenges of conducting environmental restoration efforts under conditions of significant uncertainty. SAFER was developed primarily by integrating the data quality objectives (DQOs) process with the observational approach. The intent of this effort was to provide a consistent and comprehensive streamlining approach that illustrated the collaborative benefits of the two approaches.

SAFER is based on the need, from both a scientific and engineering perspective, to make decisions under uncertain conditions while maintaining progress throughout the environmental restoration process. SAFER is derived from approaches originally used in environmental quality assurance (Blacker et al., 1990) and geotechnical engineering (Peck, 1969). (Further information on these approaches can be found by consulting the *Sources*.) To further facilitate progress, DOE also recognized the need to involve groups with vested interests (e.g., regulators, Native Americans) in environmental restoration activities into each step of an environmental restoration project, and thus incorporate frequent, significant input from stakeholders as a major element of SAFER.

Developed for DOE's environmental restoration effort, SAFER was designed to be aggressive, yet compatible and compliant with existing environmental regulations [e.g., Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Resource Conservation and Recovery Act (RCRA)].

Integration with the RI/FS Process

In this guidance, SAFER is a **methodology** used to help streamline the Remedial Investigation/Feasibility Study (RI/FS) process and to manage changes to the selected remedy. As such, SAFER concepts have been thoroughly integrated into the previous six modules that provide guidance on conducting the RI/FS and remedy selection **process**. The RI/FS and remedy selection process modules do not explicitly identify or distinguish the SAFER concepts that are used. They are presented as DOE intends to use them—as an integral part of the environmental restoration process.

This module does not repeat the process guidance provided in the first six modules; it identifies and discusses the major elements of SAFER used during an RI/FS and remedy selection. However, SAFER also is applicable as a streamlining methodology throughout Remedial Design/Remedial Action (RD/RA). This module identifies and discusses major elements of SAFER used during RD/RA. Although guidance on conducting the RD/RA process is not a part of the guidance in the earlier modules of this document, the SAFER techniques used during RD/RA are provided in this module to ensure a comprehensive understanding of SAFER's full capability for identifying and managing uncertainty throughout the environmental restoration process.

Organization

Module 7 is divided into three submodules

- 7.1 SAFER Introduction
- 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study
- 7.3 SAFER During Remedial Design and Remedial Action

Module 7 Streamlined Approach For Environmental Restoration (continued)

The format of Module 7 is different from the first six process modules—it does not follow a graphical, flowchart process. Module 7 is divided into three submodules that provide text and companion figures to identify and discuss SAFER's main elements. This module provides an understanding of the major SAFER elements and the role they play in each phase of the CERCLA process.

Sources

- 1. Blacker, S., D. Neptune, B. Fairless, and R. Ryti, September 1990, "Applying Total Quality Principles to Superfund Planning," in *Proceedings of the 17th Annual National Energy Division Conference, American Society for Quality Control*.
- 2. Dailey, R., D. Lillian, and D. Smith, 1992, "Streamlined Approach for Environmental Restoration (SAFER): An Overview," in *Proceedings of the 1992 Waste Management and Environmental Sciences Conference*, April 9-11, 1992, San Juan, Puerto Rico.
- 3. Gianti, S., R. Dailey, K. Hull, and J. Smyth, 1993, "The Streamlined Approach For Environmental Restoration," in *Proceedings for Waste Management 1993*, Vol. 1, p. 585ff.
- 4. Hull, K., and D. Neptune, September 1991, "The Data Quality Objective Process," *Journal for Quality and Participation*, pp. 72-78.
- 5. Peck, R. B, 1969, Ninth Rankine Lecture-"Advantages and Limitations of the Observational Method in Applied Soil Mechanics," *Geotechnique* 19, No. 2, pp. 171-87.
- 6. Smyth, J. D., J. P. Amaya, and M. S. Peffers, 1992, "DOE Developments, Observational Approach Implementation at DOE Facilities," in *Federal Facilities Environmental Journal*, Autumn, pp. 345-355.
- 7. U.S. EPA, 1990, Total Quality Management (TQM) and Quality Assurance (QA) in Superfund, OSWER Directive 9242.6-08.
- 8. U.S. EPA, April 1990, Interim Final Guidance on EPA Oversight of Remedial Designs and Remedial Actions Performed by Potentially Responsible Parties, EPA 540/G-90/001, OSWER Directive 9355.5-01.
- 9. U.S. EPA, June 1992, *Remedial Action Report: Documentation for Operable Unit Completion*, OSWER Directive 9355.0-39FS.
- 10. Wallace, W. A., 1988, "Engineering Under Uncertainty: A New Perspective on the Cleanup of Hazardous Waste Sites," presented at Joint CSCE-ASCE National Conference of Environmental Engineering, Vancouver, B.C., Canada.
- 11. Wallace, W. A., 1991, "New Paradigms for Hazardous Waste Engineering," *Remediation*, Autumn, pp. 419-445.

Submodule 7.1 SAFER Introduction

7.1 SAFER Introduction | 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study | 7.3 SAFER During Remedial Design and Remedial Action | 7.1 SAFER Introduction | • Assumptions | • Framework

• Essential Elements

Submodule 7.1 SAFER Introduction

Background

The underlying assumption in SAFER is that inherent uncertainty will always be a factor in environmental restoration activities. SAFER groups environmental restoration uncertainty into three broad areas: site conditions, remedial technology performance, and regulatory requirements. To be effective, the CERCLA process must develop and implement solutions that address waste-site problems while managing these uncertainties.

The process of developing and implementing solutions, and managing uncertainty is dependent on the environmental data measurement system. Uncertainty in data collection and evaluation is associated with any measurement system.

The uncertainty associated with the measurement systems can be identified and measured and to an extent, **reduced**. Additional data can be collected, more representative data can be collected, and more precise analytic methods can be used at any point in the environmental restoration process. However, despite the effort to reduce uncertainty through careful design of sampling and analysis efforts, uncertainty will remain in knowledge of site conditions, the ability of a remedial technology to perform, and the regulatory requirements (e.g., potential changes in cleanup goals). These remaining uncertainties must be **managed**.

SAFER is a methodology that allows an explicit (i.e., formal and documented) optimization between reducing uncertainty in environmental restoration decisions and managing uncertainty during remediation. The objective is to identify how much effort should be put into reducing uncertainty through data collection and into managing uncertainty, to facilitate continued prudent progress toward remediation. This balance is highly dependent on site-, technology-, and regulatory-specific conditions.

An introduction to SAFER terminology and concepts follows.

SAFER Terminology

SAFER uses terminology derived from the observational approach and the DQO process. The following list of definitions introduces many of the SAFER terms used in this module.

DOE project team (**also, internal project team**). The group responsible for conducting the RI/FS at a DOE site. As used in this guidance, the DOE project team includes DOE personnel and DOE contractors who will conduct the RI/FS and develop its reports.

Extended project team. The individuals (internal and external) who will interact throughout the RI/FS project and who are responsible for directing, managing, conducting, and approving an RI/FS at a DOE facility. As used in this guidance, the extended project team is composed of the DOE project team, EPA and State regulatory staff, and relevant public interest groups.

Stakeholder. Any person or group interested in or affected by an RI/FS project conducted at a DOE facility.

Submodule 7.1 SAFER Introduction (continued)

Probable Conditions. The best understanding of what the data and other information suggest as the conditions (e.g., contaminants, pathways, receptors) and constraints that a remedy must address or meet (e.g., regulatory requirements). Based on probable conditions, problems that require remediation are identified as the focus of the RI/FS project.

Uncertainty. Questions or gaps in knowledge that affect the ability to remediate the site. Uncertainty that does not impact remediation of the site is not of interest to SAFER. SAFER attributes uncertainty to the following:

- Measurement system limitations in accurately collecting, analyzing, and evaluating environmental data
- Incomplete knowledge of site conditions
- Inability to predict remedial technology performance
- Changing or unclear regulatory requirements

Uncertainties are addressed in one of two ways: (1) the measurement system is enhanced (e.g., additional data collection, better analytical techniques) to reduce the uncertainty to acceptable levels or (2) the uncertainty is acknowledged and expressed as a reasonable deviation to probable conditions. A contingency plan is then developed to use in the event that the physical or chemical nature of the site does not permit implementation of the alternative as originally envisioned (i.e., the reasonable deviation occurs).

Measurement System. Defines what is measured, how it is measured, and how it is evaluated. In environmental restoration, measurement systems usually consist of what environmental data should be collected, how it should be collected in the field, how samples should be packaged and transported, how samples should be analyzed in the laboratory, and how data will be evaluated. Measurement systems are used during the RI, in treatability studies, and in monitoring site conditions during remediation.

Decision Rule. Establishes the relationship between the decision that is being made and the types and quality of data collected to support the decision. Decision rules generally are "If . . , then . . ." statements that establish what decisions or actions will be taken depending upon the data evaluation. Development of decision rules forces a focus on the real need for a particular type of data and tends to reduce data collection to an essential minimum.

Decision rules are based on probable conditions. Formulation of a decision rule enables stakeholders to specify an acceptable **limit** to total error in the measurement system. By carefully designing measurement systems, the uncertainty that results from collection, analysis, and evaluation can be reduced but not eliminated. This streamlines the RI/FS by explicitly identifying the following with stakeholder agreement:

• The raw data to be collected and how they will be combined into a result suitable for decisionmaking

Submodule 7.1 SAFER Introduction (continued)

- The basis for what the result will be compared with, or how it will be evaluated (e.g., action level, cleanup goal)
- The action that will be taken on the basis of this evaluation

Deviation. Possible alternative conditions (regulatory, technical, site) to probable conditions based on current understanding.

Reasonable deviation. A deviation from the probable conditions that has been judged by the extended project team as sufficiently likely to be encountered such that a contingency plan should be developed.

Unreasonable deviation. A deviation from probable conditions that has been judged by the stakeholders to be unlikely, or a deviation for which a contingency plan cannot be identified. The latter type of unreasonable deviation usually results in an identified data gap that will have to be filled through data collection efforts.

Contingency plan. A plan of action pre-arranged in the event that a reasonable deviation from the probable site conditions is encountered during remediation. A contingency plan is one of the primary means by which an uncertainty is addressed under SAFER.

Monitoring plan. During remediation, the site is monitored to detect any of the identified reasonable (potential) deviations. The monitoring plan is developed in concept during the FS and in detail during the RD phase. The monitoring plan may require modification following implementation of a contingency plan.

Organization

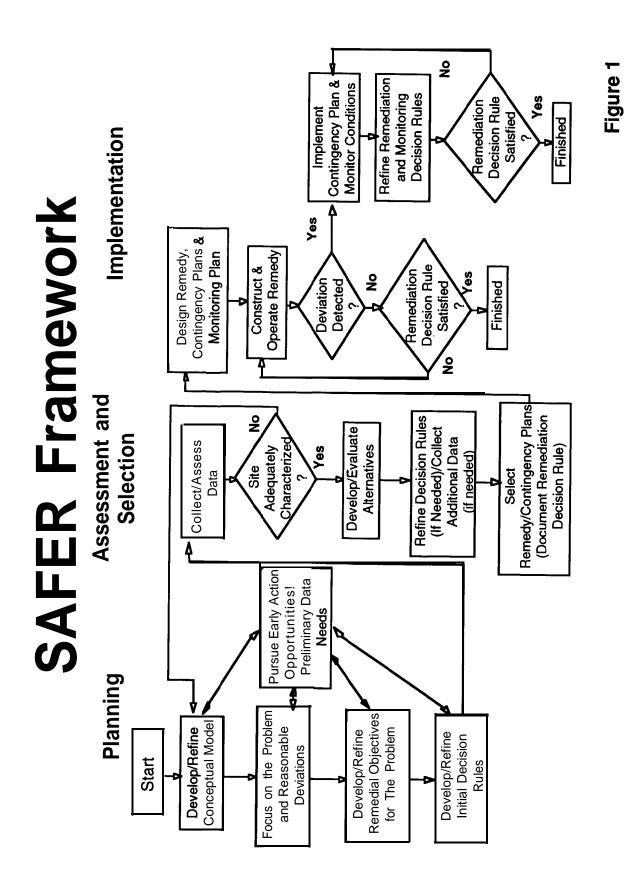
Submodule 7.1 discusses the following:

- SAFER Assumptions
- SAFER Framework
- SAFER Essential Elements

Assumptions

Uncertainty in environmental restoration exists at project, programmatic, operations facility, and department levels. SAFER was developed to focus on project-level [i.e., operable unit (OU)] issues. Additional information on tenets of the parent approaches that can be extended to uncertainty at other levels can be found by consulting the Sources [e.g., (Wallace, 1991)].

Administrative uncertainty (e.g., Congressional funding, contract vehicles, and management issues) potentially impede progress in environmental restoration activities at the project level. Although these issues have regular and significant impact on environmental restoration projects, they are beyond the scope of SAFER. SAFER is designed to achieve progress toward a remedial goal, mutually agreed upon by stakeholders, while managing uncertainties in site knowledge, remedial technology performance, and regulatory requirements. SAFER does not address the following:



Submodule 7.1 SAFER Introduction (continued) 7-12

Submodule 7.1 SAFER Introduction (continued)

- Determining if the waste site is a perceived problem [e.g., Hazard Ranking System (HRS) scoring and inclusion on the National Priorities List (NPL)]. The SAFER process begins at the point where available data are evaluated to best determine existing conditions at the waste site. The determination that the waste site requires further action (e.g., limited investigation, no-action, interim remedial action, remedial action) to address a perceived problem is assumed.
- Determining which regulatory framework (e.g., CERCLA, RCRA) applies. SAFER is sufficiently flexible to operate under a variety of regulatory authorities [e.g., Uranium Mill Tailings Remedial Action Program (UMTRAP), CERCLA, Formerly Utilized Sites Remedial Action Program (FUSRAP), RCRA]. SAFER assumes that the appropriate regulatory authority for the waste site has been determined.
- **Obtaining project funds.** Any environmental restoration project is dependent upon adequate and timely funding. SAFER does not address funding uncertainties; it assumes that the process of requesting and obtaining secure funding will not be a problem.
- Identifying stakeholders. Stakeholders play an integral role at DOE facilities, particularly in environmental restoration activities. SAFER encourages and presumes active stakeholder participation. SAFER assumes that the stakeholders and their roles in the environmental restoration process have been previously defined on a site-specific basis for a particular environmental restoration project.

Framework

Figure 1 shows the entire SAFER process in a CERCLA regulatory framework. Although in this diagram SAFER appears to be a linear process, it is similar to the CERCLA process in that both are highly iterative. For example, data collection efforts during the RI are based on current site understanding and are designed to fill identified data needs such as requirements for evaluating potential remedial actions. After data collection and evaluation, the site understanding (including further data needs) changes. Similar iterative or feedback processes exist throughout the SAFER process.

Scoping, or planning, is more strongly emphasized in the SAFER approach when compared with the way CERCLA projects have been performed in the past. A focused RI/FS study is facilitated by the increased effort that is put into Scoping. For instance, SAFER encourages maximizing the use of available data to focus the RI and to converge quickly on a range of realistic remedial alternatives. Focusing an RI/FS provides a means for accelerating the initiation of remediation.

Addressing issues such as remedial action objectives (RAOs) and potential remedial actions early in the process also allows a focused RI/FS. Aggressive remedy assessment and selection is possible with SAFER because these processes are conducted on the basis of the probable conditions at a waste site. Possible deviations to probable conditions are identified and addressed if they inhibit the ability to identify the appropriate remedy or potentially inhibit implementation and operation of the remedy. Uncertainties, which can lead to deviations, are addressed in two ways-by elimination through data collection or by management through development of contingency plans. Decision rules are formulated to clearly identify data needs and data uses. When very explicit data needs are derived from the decision rules, the data collection efforts are strongly focused and reduced to the essential minimum. Contingency plans are developed for use during remediation to manage certainties and associated potential deviations that are not eliminated through data collection.

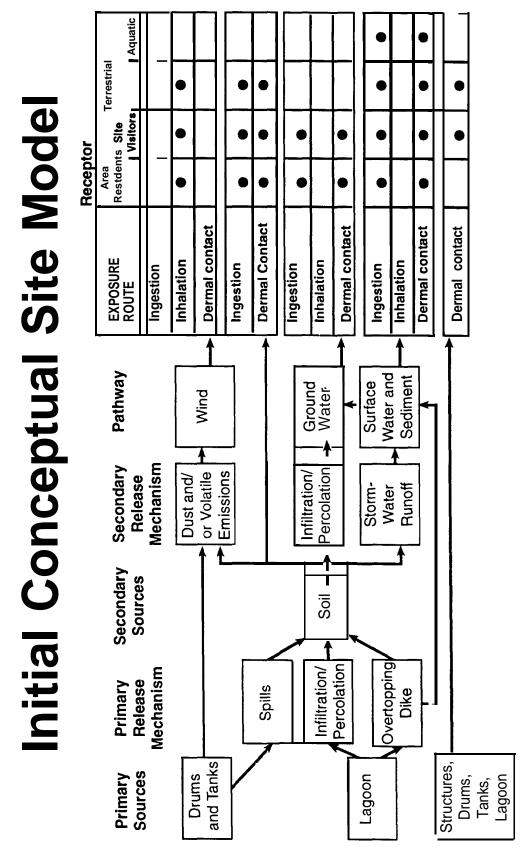


Figure 2

Submodule 7.1 SAFER Introduction (continued) 7-14

Submodule 7.1 SAFER Introduction (continued)

During detailed design of the remedial action, contingency plans and monitoring plans are also designed in more detail. During implementation, monitoring systems identify the need to implement a specific contingency plan. The contingency plan provides the necessary modification of the remedial action to help ensure that progress toward the remedial goal continues with minimal delay. Decision rules are used to identify data that are collected during monitoring to identify deviations and to determine when the remedial goals have been accomplished.

Essential Elements

SAFER has four essential elements: (1) defining and using a conceptual model to provide a foundation for remedial planning and action; (2) planning and conducting assessment, remedy selection, and remedial action on a "Learn-as-you-go" basis; (3) recognizing the management of uncertainty as a key to conducting each phase of the remedial process; and (4) recognizing the role and contributions of stakeholders. If these elements are not formally part of the environmental restoration activity (i.e., documented in compliance reports), then SAFER is not being applied.

The application of each element is dynamic during the environmental restoration process. For example, based on the initial understanding of regulatory requirements and site conditions, site uncertainty might appear to be readily manageable during remediation. However, following a limited field investigation (LFI), the implications of the uncertainty may result in the need for additional investigation to reduce uncertainty to manageable levels. The other elements also will be dynamic throughout the SAFER process.

Element 1-Conceptual model as a foundation for the environmental restoration process. A summary representation (pictorial, written, or both) of key site conditions, including likely contaminant sources (and their physical and chemical characteristics), contaminated media, pathways, and receptors. Figure 2 shows a simplified example of one type of conceptual model. (Submodule 1.2, Note C, provides a detailed example of a conceptual model.)

The conceptual model is initially based on existing site information, key assumptions, and extended project team perspectives, and evolves as remedial planning and action proceed. SAFER uses the conceptual model as a primary tool to streamline planning and remediation. SAFER focuses on identifying relevant uncertainty key to remediation and on testing and verifying the uncertainty and assumptions in the conceptual model. Thus, the conceptual model facilitates focus on problem(s) and their potential solutions and highlights principal uncertainty.

The conceptual site model is a dynamic picture of current site understanding. It requires periodic refinement as new information is gained throughout the remedial process. Revisions are necessary as assumptions based on available data are confirmed, made uncertain, or proven false by the introduction of new information.

As a tool, the conceptual site model provides identification and representation of uncertainties in the areas of concern to remediation (e.g., waste sources, pathways, release mechanisms). The conceptual model helps make data gaps apparent. Data gaps result from uncertainties in characterization information (e.g., demographics for risk, fate, and transport data; physical soil properties; contaminants of concern). A data gap is any insufficiency in information to support the baseline risk assessment, identification of applicable or relevant and appropriate requirements (ARARs), and development and evaluation of remedial alternatives.

Submodule 7.1 SAFER Introduction (continued)

Element 2-Plans and designs based on learn-as-you-go. The remedial process is inherently dynamic–uncertainty will continue to exist throughout the remedial process, and will change as remediation proceeds.

Each step of the SAFER process builds, in specific ways, on the output of earlier steps (see Figure 1). Learning is constantly occurring throughout the remedial process, therefore by necessity, SAFER allows for new knowledge to be incorporated throughout the process. This will result in refining earlier decisions. Designed to be an iterative process, SAFER makes extensive use of feedback loops in the management of uncertainty.

Three examples of feedback loops in SAFER: (1) During planning, the formulation of a decision rule may indicate that a different problem is of interest. (2) During assessment, alternatives evaluation may indicate that a deviation thought to be reasonable and manageable cannot be handled by developing a contingency plan. This results in the consideration of additional potential remedial alternatives or the identification of new data needs. (3) During remediation, actual performance of the remedy (as indicated by monitoring) may require revised remediation goals or remediation decision rules.

Through learn-as-you-go, SAFER emphasizes optimizing the management of uncertainty, intervening at the best points (as identified by the extended project team) in the process to manage uncertainty with the appropriate techniques (as identified by the extended project team) to ensure the proper balance between planning and action.

Element 3–Recognition of explicit uncertainty and development of management techniques. At any point during the RI/FS/RD/RA process, data deficits and knowledge deficits exist that affect the ability to remediate the site. Uncertainty that does not impact remediation of the site is not of interest to SAFER. The fundamental sources of uncertainty are as follows:

- Incomplete knowledge of site conditions. Best knowledge of site conditions is summarized in the conceptual model.
- Inability to predict remedial technology performance. While the performance of some
 remedial technologies may be well understood in controlled environments, such as laboratory
 tests, uncertainties about site conditions render prediction of remedial technology
 performance in the field as more uncertain. Other especially innovative technologies may not
 be as well understood, which results in considerable additional uncertainty about technology
 performance.
- Changing or unclear regulatory requirements. The regulatory environment that DOE environmental restoration activities operate within is dynamic. Final interpretations or determinations of regulatory issues and constraints (e.g., assumed future land use, cleanup criteria) contribute to uncertainty about remedial goals.

Note that each of these areas is dependent upon data to determine probable conditions or probable performance. A measurement system must be defined to provide and evaluate the needed data. Measurement systems are also sources of uncertainty. By carefully designing measurement systems, uncertainty that is inherent in collection, analysis, and evaluation can be reduced and managed, but not entirely eliminated.

For environmental restoration to progress, the only choice is to operate under conditions of uncertainty. Stakeholders must be able to define (1) the overall level (cumulative of all sources) of uncertainty that is

Submodule 7.1 SAFER Introduction (continued)

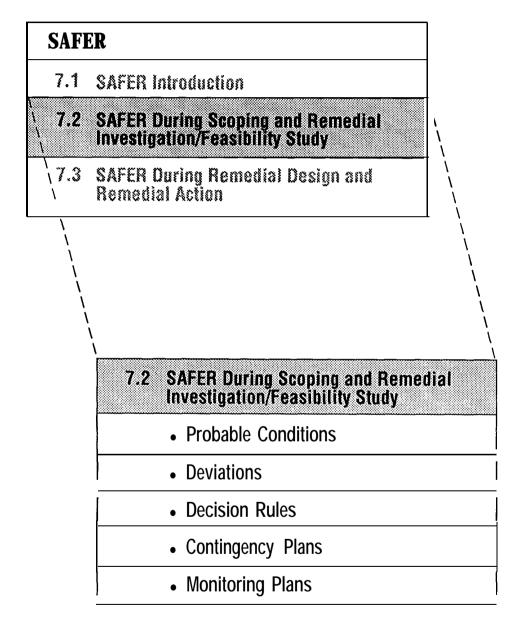
acceptable at each point in the process and (2) the techniques for managing the uncertainty that will be applied at each point in the process. In general, the two approaches for dealing with uncertainty are (1) **reducing** it by careful design of a measurement system (typically data collection) and (2) **managing** it by developing contingency plans.

Optimization of uncertainty management is different at each site. It may be sensible to collect a "great amount" of data during planning to reduce uncertainty (see Submodule 8.1) or it may be likewise sensible to rely on a remedy that allows uncertainty to be readily managed during remediation (see Submodule 8.2).

Element 4–Stakeholders. Traditionally, the extended project team and other stakeholders play an instrumental role in identifying applicable regulatory frameworks, establishing budgets and schedules, and determining information requirements. In the SAFER framework, stakeholders continue to perform these functions, but they also make additional contributions that are crucial to the effective management of uncertainty. These contributions include the following:

- Participation in developing the overall site-specific strategy for dealing with uncertainty
- Input to and understanding and acceptance of the conceptual model
- Consensus on actual site problems to be addressed
- Determination of future land use and other issues pertinent to the establishment of RAOs
- For each data collection effort, description of the qualitative consequences of error, which are translated into quantitative data performance criteria by the extended project team
- Agreement on reasonable deviations and associated contingency plans
- Acceptance of a decision document that includes all of the output described above
- Active monitoring and involvement about uncertainty issues as remedial action proceeds

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study



Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study

Background

The environmental restoration process consists of two broad phases that, to be effective and efficient, must be considered as a continuum: defining the risk to human health and the environment posed by the site, determining the appropriate remedy to the perceived problem, and implementing that remedy. In CERCLA, the process of characterizing the site, defining the risk, and determining the remedy includes Scoping, RI/FS, and remedy selection. SAFER uses the concepts of probable conditions, deviations, decision rules, and contingency plans to achieve enhanced planning, focused investigations, and aggressive alternative assessment and remedy selection. SAFER streamlines the CERCLA process by providing a framework to optimize the management of uncertainty through the use of a conceptual model, incorporating new information as it is learned, and integrating the extended project team in the decisions about characterization and remediation.

This module highlights the role of SAFER concepts in streamlining the Scoping/RI/FS process.

Organization

Submodule 7.2 discusses the following:

- Probable Conditions
- Deviations
- Decision Rules
- Contingency Plans
- Monitoring Plans

In addition, more detailed information is provided in the following notes:

- Note A-Discomfort Curves
- Note B-Deviations and Contingency Plan Development

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Probable Conditions

The probable conditions of the site establish the focus for the project; they are the basis for Scoping and the RI/FS. This acts to streamline Scoping/RI/FS by providing the basis for decisionmaking by the extended project team in areas such as prioritizing problems the remedy must address, alternatives evaluation, ARARs determination, risk assessment, and remedy selection.

Scoping. During scoping, probable conditions are based on available data, the working hypothesis, and assumptions and conjecture about the waste site. The probable conditions should be defined as completely as possible, short of mere guessing, during Scoping. Uncertainties about probable conditions are noted. Preliminary evaluations, such as preliminary ARARs identification, are based on the initial probable conditions. Data needs are the result of the inability to make decisions (e.g., what are the RAOs?) based on the existing understanding of probable conditions. This results in focusing data collection activities on confirming probable conditions.

Summary information of the site's probable conditions and uncertainties form the conceptual model. Probable conditions will be revised on the basis of new information gained during the RI/FS. Similarly, the conceptual model will be revised. The conceptual model is the best overall picture of the probable conditions. The extended project team will exercise judgment to define what is probable, unlikely, and uncertain.

Remedial Investigation. One of the primary purposes of the RI is to further develop, refine, and confirm the problems to be addressed by collecting specific data required to make decisions about waste-site restoration. After the RI is complete, the probable conditions should be known to the extent necessary to meet specified expectations of the extended project team. For example, "Are the probable conditions defined sufficiently to support decisions that will be made on the basis of the baseline risk assessment?"

The conceptual model is updated on the basis of new understanding of probable conditions.

Feasibility Study. The probable conditions are the basis for (1) development, screening, definition, and evaluation of remedial alternatives; (2) the baseline risk assessment; and (3) the ARARs evaluation. These three evaluations are conducted under the assumption that the probable conditions are the actual conditions met in the field.

The extended project team again provides the judgment on the adequacy of probable conditions to support these evaluations. Note that "adequacy" in SAFER is defined by the extended project team.

The evaluations may be iterative to the extent that probable conditions are based on new information from the RI. Basing these evaluations on probable conditions allows for rapid convergence on likely remedial alternatives, relative to waiting for "complete characterization."

Deviations

Deviations to probable conditions represent uncertainty (e.g., site conditions, technology performance, regulatory requirements) that must be addressed during the RD/RA. The uncertainty represented by deviations is the uncertainty that could not be reduced through data collection, or did not need to be reduced because it could be managed during the RD/RA.

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Identifying which deviations are reasonable and preparing contingency plans to address them is a primary SAFER technique. This process of identifying reasonable deviations streamlines the RI/FS by eliminating the need to exhaustively attempt to eliminate uncertainty.

Scoping. Possible deviations to probable conditions are first identified as uncertainties in the probable conditions. At this point, deviations will represent a wide range of alternative conditions because of the uncertainty of site conditions. Deviations to probable conditions are easily identified as a result of uncertainties portrayed in the conceptual model.

Deviations do not represent data needs—data collection is focused on confirming probable conditions and remedial problems, not on confirming deviations. Deviations are found to exist when probable conditions are not confirmed: These then become revised probable conditions. During Scoping, data needs are based upon the necessity to reduce uncertainty with decisions based on probable conditions.

Remedial Investigation. The ensemble of possible deviations is revised based on the revised understanding of probable conditions. As probable conditions are confirmed the possible deviations are reduced in number and magnitude. This process results in identifying reasonable deviations to the probable conditions based on site understanding. The extended project team defines what constitutes a reasonable deviation based on understanding of site conditions. Unreasonable deviations to probable site conditions are discarded. The process of identifying reasonable deviations streamlines the RI/FS by focusing on uncertainty that realistically could impact the process of restoring the site.

The conceptual model, revised on the basis of new information, provides the extended project team and other stakeholders with the ability to distinguish between reasonable and unreasonable deviations based on site understanding.

Feasibility Study. The ensemble of reasonable deviations are further defined during the FS by considering as "reasonable" only those deviations that will impact the remedial alternatives under consideration. Unreasonable deviations in this instance are deviations that may be possible based on site understanding, but do not impact the remedial alternatives. These technology-based unreasonable deviations also are discarded. Note that technology-based unreasonable deviations are a function of the technologies being considered as part of the remedial alternative. For example, although the concentration of lead in the soil may not impact ex-situ stabilization, it does impact incineration.

Unreasonable deviations also result from the inability to identify specific contingency plans to manage the deviation. This type of unreasonable deviation results in the necessity to further define probable conditions, or to identify shortcomings of the remedial alternatives. If methods to manage the reasonable deviations cannot be identified (i.e., contingency plans), specific data needs may result.

This process of continuously refining reasonable deviations based on new information acts to streamline the RI/FS by focusing only on uncertainties that must be managed, discarding uncertainties that are irrelevant to waste-site restoration.

During the FS, the extended project team continues to define "reasonableness," and the conceptual model continues to provide a ready tool to assess "reasonableness."

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Decision Rules

Decision rules, based on problems that probable conditions indicate as existing, summarize how uncertainty will be reduced by the data measurement system. Decision rules proactively and explicitly tie decisionmaking to data needs and uses. This streamlines the data collection process by ensuring that analytic and field techniques are commensurate with the data use (i.e., decision) and ensuring that these data are being used to support a specific decision or set of decisions. Note that this does not necessarily imply less sampling–rather it implies identifying optimal data measurement techniques for decisions that must be made as part of the RI/FS. Data collection to reduce uncertainty must always be balanced against the ability to manage uncertainty (via the contingency plan) during the RD/RA.

Decision rules also act to streamline because the extended project team explicitly defines what data measurement systems are adequate for decisionmaking. A previously defined "stopping rule" minimizes the opportunity for extended project team miscommunication about when to stop sampling.

Scoping. During Scoping, decision rules generally deal with characterization issues at a minimum. These decision rules will establish the focus of the investigation. For example, the decision for the volume of contaminated soil to address will be formulated into a decision rule by identifying the type of data to be collected, the quality and quantity of samples, the measurement technique, the basis for the decision, and the action resulting from the decision (e.g., this volume will be remediated). Characterization issues may be resolved with "one-pass" data collection as another means of streamlining.

Opportunities for early action (e.g., removal actions, interim remedial actions) are always available as another means of streamlining. When opportunities for early actions arise, decision rules may begin dealing with remediation decisions (e.g., what soil to remove, when to stop digging). In a full-scale RI/FS, these issues will typically be dealt with during the FS.

The extended project team will specify the level of uncertainty they require in making the characterization decision. This may be a phased decision–first determining if action is required (i.e., characterization sufficient to support baseline risk), with following decisions focused on sufficient characterization to support development and evaluation of alternatives and ARARs analysis. Translating stakeholder "comfort" with making decisions to uncertainty constraints on data measurement systems is difficult. Submodule 7.2, Note A, provides additional detail on one SAFER technique–discomfort curves.

Decision rules that are used in the work plan will help to define the Sampling and Analysis Plan (SAP) and the Quality Assurance Project Plan (QAPP).

Remedial Investigation. The data measurement system necessary to support sufficient site characterization has been pre-established by the extended project team by formulation of decision rules during Scoping. Characterization decision rules and associated data needs are revised on the basis of new information.

Feasibility Study. Decisions begin to focus on remediation issues, such as the necessity for further action, when the site is restored, and how determining when a deviation is occurring.

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Decision rules for remediation goals are directly related to the choice of remedial alternative because of the individuality of technologies (e.g., in situ stabilization has different remediation results than does ex situ treatment). Remediation decision rules will be finalized in the Record of Decision (ROD) when the selection of the remedial alternative is finalized.

Decision rules for identifying deviations during remediation are based on how to distinguish deviations from probable conditions. These also will be directly related to the type of technologies that are a part of remedial alternatives. During the FS these monitoring decision rules are only conceptually defined. They are defined in detail during the RD/RA.

Contingency Plans

Contingency plans are part of managing uncertainty during the RD/RA. Contingency plans are technology-specific and based on the definition of reasonable deviations. The ability to manage uncertainty during the RD/RA streamlines the RI/FS by reducing the need to continually refine probable conditions by collecting data until minimal uncertainty exists. The net result is to ensure that the data collection that does occur is minimized by balancing the need to reduce uncertainty with the ability to manage it.

Contingency plans play only a conceptual role during the RI/FS. They are defined in detail during the RD/RA.

Scoping. Contingency plans are technology-specific. Contingency plans do not play a large role until technologies can be adequately defined. Their existence may be evaluated as a part of determining whether uncertainties in probable conditions can be managed. (See Submodule 7.2, Note B.)

Remedial Investigation. Contingency plans have a minimal role in the RI.

Feasibility Study. The need to actually implement a contingency plan is identified by evaluating the impact of reasonable deviations on likely remedial alternatives during the FS. During the FS, contingency plans have to be sufficiently developed to allow evaluation of the remedial alternative. Contingency plans are defined in detail during the RD/RA. The accompanying graphic provides some example contingency plans during RI/FS. (Also see Submodule 5.1, Note B.)

During the FS, two options exist if a contingency plan cannot be identified for a deviation: (1) additional data can be collected to further reduce the uncertainty in the probable conditions and technology performance, therefore better defining or eliminating the reasonable deviation. (2) The alternative (technology) becomes an unlikely remedial alternative based on evaluation criteria. The FS is thus streamlined by helping to focus on remedial alternatives that can address probable conditions and reasonable deviations. This eliminates alternatives that cannot adequately manage existing uncertainty, or identifies the need to further reduce the uncertainty before the alternative can be effective.

Submodule 7.2, Note B, provides a template for assessing deviations and the need for contingency plans.

Submodule 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Monitoring Plans

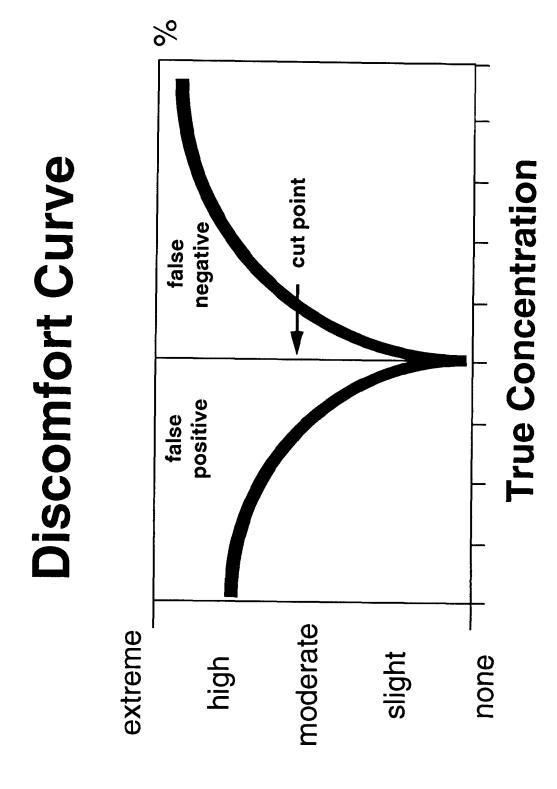
Monitoring plans are part of the ability to manage uncertainty during the RD/RA by detecting deviations. Two parts of monitoring are important: (1) identifying the deviation that is occurring and (2) identifying which contingency plan is necessary to modify the remedy.

Like contingency plans, monitoring plans are to a great extent, technology-specific. Although defined conceptually during the RI/FS, they do not play a large role in streamlining until the RD/RA.

Scoping. Monitoring plans do not play a role.

Remedial Investigation. Monitoring plans do not play a role.

Feasibility Study. Monitoring plans are sufficiently defined in concept to ensure that deviations can be monitored for and detected, and to ensure that the appropriate contingency plan is identified. Submodule 7.2, Note B, provides additional detail.



Submodule 7.2 Notes on SAFER During Scoping and Remedial Investigation/Feasibility Study

Note A.

Discomfort Curves. Decision rules specify allowable error in the measurement system by incorporating a statement of uncertainty constraints. In SAFER, uncertainty constraints are quantitative statements of willingness to accept error in decisions based on environmental data. Decision uncertainty constraints can be directly translated into data (measurement system) performance criteria. Decision rules are developed to accommodate error that is acceptable in making a decision based on environmental data (e.g., the error that is acceptable in identifying a volume of soil as contaminated). One way to discuss this type of error (i.e., the chance of being wrong) is in terms of statistical Type I (false positive) and Type II (false negative) error statements. A false positive in the above example is deciding that the soil is contaminated and that action is necessary when, in fact, the soil is clean. Measurement system error is the only contribution to overall uncertainty that is quantifiable and that can be explicitly limited. (Note that inherent temporal and spatial variability of environmental data is a source of uncertainty that can be estimated but not limited.)

Decision error tolerances depend on the specific nature of the decision (i.e., they depend on how the decision rule has been formulated). The type and quality of data needed to make the decision would vary accordingly. The acceptable error is directly dependent on the consequences of the decision, and is determined in SAFER by the willingness of the extended project team to tolerate error. Further, toleration about false positives and false negatives probably is not equivalent—depending on the specific decision and the specific implications of error. For environmental restoration, a false positive can mean taking some action and spending resources unnecessarily; a false negative can mean exposing some portion of the environment to a continuing threat.

The proper tradeoff is never obvious—it depends on the specific site, the specific decision, and the perspectives and priorities of the extended project team. SAFER manages uncertainty at this point by providing a structure through which these perspectives can be introduced, evaluated, and developed into a consensus. Once extended project team consensus is reached about a decision's qualitative error tolerances, it is a straightforward statistical process for the extended project team to translate them into the required quantitative terms of the measurement system. A variety of techniques exists for discussing error quantitatively (e.g., confidence intervals and power curves). The "discomfort curve: is a tool that has proven to be very effective as a quantification of false positive and false negative error tolerances.

The benefit of quantifying decision error is that this discomfort curve (or one of the other quantitative means for depicting decision error tolerances) provides exactly what is needed to design an optimal data collection program. In other words, a rational basis now exists for allocating measurement system error.

Submodule 7.2 Notes on SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

The accompanying figure shows a hypothetical discomfort curve. Note that the horizontal axis is labeled "true concentration"—the point (or range) that the measurement system is trying to determine. The vertical line in the middle of the diagram represents a "cut point"—the level to distinguish (e.g., the remedial goal or an action level concentration). The determination of what constitutes a cut point is dependent on the decision being made.

Note that the area to the left of this line represents a true negative. However, some portion of this area will depict false positives—the data evaluation indicates that the cut point has been exceeded when, in fact, the cut point has not been exceeded. The right side of the line represents positives, some of which will be false negatives—the data evaluation indicates that the cut point has not been exceeded when, in fact, the cut point has been exceeded.

The left vertical axis represents the extended project team's level of concern about making a wrong decision (e.g., the qualitative error tolerances). On the right vertical axis, these qualitative terms can be translated into quantitative ones; the values chosen will be site-specific.

The heart of the discomfort curve is the set of curves that depicts the stakeholder's willingness of the extended project team to tolerate error in the decision being made. Generally, the closer the true concentration is to the cut point, the lower the level of concern about error. Likewise, the further the error is from the cut point, the higher the level of concern. The same logic applies to false positives.

The shape of these curves, combined with the numerical values assigned on the right vertical axis, will determine the quantitative decision error tolerances. The implications of false positive and false negative errors are not identical; it would, therefore, be unlikely for these curves to have the same shape.

The discomfort curve is valuable because it provides specification of total allowable error. The extended project team can now propose possible data measurement systems and demonstrate whether they meet the decision error tolerances displayed by the discomfort curve (e.g., the performance of the survey design is lower than the discomfort curve at every point). The decisionmaker can then select the optimal data measurement system on the basis of cost and performance.

Conversely, the extended project team may assess that no plausible design can meet the decision rule and associated error tolerances within current budgetary constraints (i.e., the data measurement system performance curve is higher than the discomfort curve at key points). In this instance, the options are (1) to increase the budget for data collection or (2) to relax the discomfort curve. In either event, planners can point to a logical basis for their next actions.

Scoping and Assessment Template

2000	Data Needs	
	Unreasonable Deviations	
	Contingency Plans	
	Impacts on Cost, Implementation, and Effectiveness	
-	Response Time	
	Probability of Occurrence	
	Reasonable Deviations	
	Remedial Technology	
	Probable Conditions	
	Contaminants	
	Pathways	

Submodule 7.2 Notes on SAFER During Scoping and Remedial Investigation/Feasibility Study (continued)

Note B. Deviations and Contingency Plan Development. The template shown in the accompanying graphic can be used to summarize linked pieces of information involved in the evaluation of deviations and contingency plans. It can easily be created on a computer and revised and updated through the remediation process as new information becomes available. The information in the first three columns is summarized in the conceptual model.

The remainder of the template focuses on the potential deviations, to assist in developing and examining the effects of the remedial alternatives. The elements in the deviations section of the template are as follows:

- **Probability of occurrence.** At this stage (and perhaps throughout the remediation process), this assessment of the deviation is probably qualitative (e.g., high, medium, low). The objective is to identify which deviations are more likely.
- **Response time.** This is the likely time (qualitative or quantitative) between the detection of a deviation and the implementation of a contingency plan. If only a short response time is expected, the required level of design will be more detailed because little time will be available for the design if a deviation is detected. Thus, this element provides information on the level of detail required for the contingency plan.
- **Impacts on cost, implementation, and effectiveness.** These are the principal screening criteria for remedial technologies and alternatives. The evaluation of these criteria may indicate substantial impacts leading to the identification of the potential for unreasonable deviations.
- **Contingency plans.** Entries in this column specify the contingency plans for responding to all deviations.
- **Unreasonable deviations.** On the basis of the analysis in the columns to the left, unreasonable deviations may exist and must be addressed with additional data collection.
- **Data needs.** The analysis prompted by the completions of the template will help identify additional data needs for which decision rules will be formulated.

This type of table can be used to effectively communicate to the extended project team and other stakeholders the strategy of managing reasonable deviations. The extended project team will develop this table.

SAFER SAFER Introduction 7.1 7.2 SAFER During Scoping and Remedial Investigation/Feasibility Study 7.3 SAFER During Remedial Design and Remedial Action **SAFER During Remedial Design and** 7.3 Remedial Action Probable Conditions Deviations Decision Rules Contingency Plans Monitoring Plans

Background

Remedy implementation is the second phase of the environmental restoration process. In CERCLA, the process of implementing the remedy includes RD and RA. SAFER uses the concepts of probable conditions, deviations, decision rules, contingency plans, and monitoring plans to efficiently design the remedy and to prevent implementation failures by responding to actual field conditions. These field conditions will vary from the probable conditions that are used to base the RI/FS and remedy selection. SAFER streamlines the RD/RA by providing a framework to manage uncertainty during the RD/RA through the use of modifying the remedy as new information is gained according to pre-planned contingency plans that were developed by the extended project team.

One essential element of SAFER is to "learn-as-you-go." As described in Submodule 7.1 and illustrated in Submodule 7.2, SAFER allows for efficient incorporation of new information. This is only possible by carefully developing plans of action. Note the effort spent in Scoping an RI/FS (see Module 1) to ensure careful and efficient use of resources. Only with careful planning can new information be efficiently and effectively incorporated, thus providing the ability to take aggressive yet responsible action.

In a broad sense, the Scoping/RI/FS phase is the planning phase for the RD/RA. As such, all of SAFER's concepts have been introduced and considered <u>before</u> the start of the RD/RA, although not developed to the same level of detail. For example, a comprehensive understanding of probable conditions exists, while only a conceptual understanding of the monitoring plan has been developed.

As a result of the planning of Scoping/RI/FS, the extended project team and other stakeholders have agreed to a remedy and how remaining uncertainties will be managed during RD/RA. To a large extent, the RD/RA phase is the implementation of these plans. The RD/RA is streamlined because the approach and decisions have been proactively addressed.

This document (i.e., Modules 1 through 8) provides detailed guidance on the RI/FS and Remedy Selection process. Submodule 7.3 provides an overview of SAFER concepts during the RD/RA. Although not part of this document, SAFER RD/RA concepts are included to provide a complete presentation of SAFER in the CERCLA process. Detailed RD/RA guidance that incorporates SAFER concepts is forthcoming from DOE. Currently available RD/RA guidance is referenced in Module 7 *Sources*.

Organization

Submodule 7.3 discusses the following:

- Probable Conditions
- Deviations
- Decision Rules
- Contingency Plans
- Monitoring Plans

In addition, more detailed information is provided in the following notes:

- Note A-Contingency Plan Checklist
- Note B-Monitoring Plan Checklist

Probable Conditions

Probable conditions were fully developed during the Scoping/RI/FS phase. The probable conditions continue to provide the project's focus during the RD/RA phase. They are the basis for the RD and the starting point for the RA.

Remedial Design. Probable conditions, used as the basis for detailed design, are the same conditions that result from the Scoping/RI/FS phase. Limited design data gathering efforts may be necessary to support detailed design. The probable conditions are then revised on the basis of new information.

The remedy is designed to meet or accommodate the probable conditions—those conditions that are expected in the field. Normal engineering safety factors are part of the design based on probable conditions. Designing for probable conditions streamlines the RD by not forcing the design to "worst case" conditions, thus preventing overdesign of the remedy.

The conceptual model reflects the current understanding of probable conditions and provides an effective tool for communicating the intent and effect of design details to the extended project team.

Remedial Action. During RA, the probable conditions are the conditions that are expected. Actual conditions will vary from the probable conditions as they are defined at the start of the RA. Information that results from the RA will revise the probable conditions.

The extended project team interprets the new information and revise the understanding of probable conditions.

The RA transforms the conceptual model into reality as actual field conditions are identified.

Deviations

Deviations have been fully considered and developed during the Scoping/RI/FS phase to determine reasonable deviations. The RD/RA addresses the uncertainty represented by the reasonable deviations.

Remedial Design. During RD reasonable deviations provide the basis for the following:

- A monitoring plan to detect the deviation
- A contingency plan to modify the remedy if a deviation is detected

The RD is streamlined because reasonable deviations are not addressed as part of the detailed design. Contingency plans are prepared to reasonable deviations.

As specific details of the actual remedy are finalized, the deviations should be reevaluated for their technology-based reasonableness. For example, the incinerator specified in the detailed design may differ from the process option defined in the detailed alternative. Each process option responds differently to deviations. Similarly, if design investigations have provided new site information, the deviations should be reevaluated for reasonableness on the basis of the new site understanding.

As a result of information gained from a design investigation and the detailed RD, the extended project team will determine whether deviations are still reasonable

Remedial Action. Deviations are only detected during the RA. During the RA new information is monitored and evaluated. Revised understanding of actual field conditions will result as part of the evaluation process. Actual field conditions that vary from probable conditions are deviations; deviations that were determined to be reasonable during the Scoping/RI/FS phase are managed by implementing contingency plans. The extended project team and other stakeholders have previously approved of the contingency plans and should be informed of the need to use them.

Actual field conditions that vary from probable conditions and were not prepared for must be evaluated for their impact on the remedy. The extended project team will determine the required course of action. The conceptual model is revised to reflect the new understanding of the waste site.

Decision Rules

Two types of decision rules were identified as a result of the Scoping/RI/FS phase-remediation decision rules and monitoring decision rules. The remediation decision rule specifies the data measurement system criteria for determining that the remediation is complete. The monitoring decision rule will specify data requirements for detecting specific deviations and link those to specific contingency plans (i.e., a decision rule for each deviation that has a contingency plan).

The remediation decision rule was formally established as part of the ROD. In essence, it defines the restoration goal. The remediation decision rule cannot be modified without altering a legally binding document.

Monitoring decision rules were defined conceptually during the Scoping/RI/FS phase and are not part of the ROD.

During RD/RA the decision rules define the data measurement system that is used for deciding when remediation is complete and what contingency plan to implement when deviations are detected. Data quality and data quantity are directly correlated to the uncertainty that the extended project team feels is acceptable in making decisions of whether remediation is complete or deviation has occurred.

Decision rules focus RD/RA data collection during monitoring of the remedy.

Remedial Design. During the RD, the role of the remediation decision rule is to support development of the data measurement system that will be part of the monitoring system.

Understanding of the data measurement system for identifying deviations becomes more detailed as the remedies' specific process options are detailed during RD. The FS evaluations will have involved correlation of contingency plans to reasonable deviations. During RD, one of the primary roles of the extended project team is to define the data collection requirements of the decision rule. This is determined by the level of uncertainty that is acceptable to the extended project team in deciding the necessity of implementing a contingency plan.

Submodule 7.3, Note B, provides additional information on consideration of monitoring parameters to identify deviations.

Remedial Action. The remediation and monitoring decision rules are implemented through the monitoring system during the RA. These decision rules may require revision to the extent that new information results from the RA. If stakeholders determine that the remediation decision rule requires revision, a modification of the ROD may be required.

Contingency Plans

Contingency plans were developed to a conceptual level during the Scoping/RI/FS phase. Contingency plans streamline the RD/RA by providing pre-planned and pre-approved courses of action in the event that a deviation to probable conditions occurs. The need to stop implementing the remedy is minimized while decisions are made about what is necessary to correct the deviation.

Remedial Design. Contingency plans are defined in detail sufficient to manage the reasonable deviations during implementation of the remedy. Detailed consideration of the contingency plans is possible only during the RD because design details are now specified on the basis of probable conditions. The level of design that is necessary for contingency plans was addressed conceptually during FS. This is now revised on the basis of specific remedy design details. On the basis of probable conditions, the extended project team conducts this evaluation to determine which contingency plans will be included with the design in contract bid documents. The extended project team also determines the necessary level of design for contingency not included in the contract bid documents. Submodule 7.2, Note B, provides additional information on contingency plan evaluation criteria.

During the RD, the contingency plans should be developed to include a complete strategy to smoothly implement a modification to the remedy. Submodule 7.3, Note A, provides a strategy checklist for contingency plan development.

Remedial Action. Contingency plans are implemented as decision rules specifically during the RA. Minor modifications to contingency plans probably will be necessary as actual field conditions are discovered that differ from the probable conditions and from the reasonable deviations as they are conceptually defined. The extended project team and other stakeholders expect that these minor modifications are necessary.

Although unlikely because of the screening process, actual field conditions could result in unreasonable deviations from the expected probable conditions. Because they were identified as unreasonable deviations, no contingency plan was prepared to modify the remedy. However, the SAFER process of integrating stakeholders and constantly revising the approach on the basis of new information provides a framework for reacting to the unexpected field conditions in a controlled manner.

Monitoring Plan

The monitoring plan was developed conceptually during the Scoping/RI/FS phase.

Upon implementation, the monitoring plan is a monitoring system. Monitoring system requirements are defined by the remediation decision rules and the monitoring decision rules. The decision rules provide a basis for a focused monitoring system, which results in collecting information that is relevant only to the RA. The monitoring system is the data measurement system for the RD/RA.

Remedial Design. The monitoring system is defined in detail during the RD. The monitoring system will be specified to a sufficient level so that a contractor can implement it. It will be included as part of the construction bid documents. Submodule 7.3, Note B, provides additional detail on monitoring systems.

Remedial Action. Monitoring for deviations begins during construction, as described in the monitoring plan. Monitoring system performance begins when construction of a remedial technology (e.g., a cap, incinerator, or groundwater extraction and treatment) begins. Sampling to prove cleanup efficacy may occur during operation of a remedy (e.g., pump and treat, excavation) or may be conducted after construction is complete (e.g., cap).

Submodule 7.3 Notes on SAFER During RD/RA

Note A.Contingency Plan Checklist. A contingency plan should include a complete strategy for what needs to be accomplished to smoothly implement a modification to the selected remedy in response to a deviation. The goal of the strategy is threefold: (1) document the required scope of the contingency plan for procurement purposes; (2) allow as much preplanning as possible to allow effective, proactive response to deviations; and (3) enhance the understanding of the extended project team about processes involved in implementing each contingency plan. The strategy should include the following:

- Who is notified if a deviation occurs. The extended project team and other stakeholders are to be notified if implementation of a contingency plan is necessary. At a minimum, notification should consist of an accounting of the deviation, its impact, and the contingency plan to be used to modify the remedy. The strategy should indicate the appropriate level of compliance [e.g., notice to Administrative Record, Explanation of Significant Difference (ESD), or ROD Amendment] for documenting the various contingencies that may be used.
- Conceptual model revisions. New site information is gained during remediation. If a deviation occurs, the previous conceptual site model will require revision. The strategy should include the protocol for initiating conceptual model revisions and review with the extended project team.
- Cleanup criteria and decision rules modifications. Implementation of contingency plans in response to deviations (e.g., a drastic increase in volume of contaminated soil, a new contaminant) may result in modification of cleanup criteria. These should be anticipated and documented in the strategy, and communicated to the extended project team. The remediation decision rule will require modification in response to the cleanup criteria modification. The strategy should include the protocol for effecting this change.
- **Final design and implementation details and approvals.** This includes the rationale of design detail for each contingency. The strategy should outline (in concept) the level of design that will be required before implementation of the contingency is possible. The strategy should include the evaluation results that determined the level of design detail.
- Coordination with initial or primary remediation contractor. The strategy should document the lines of communication that are necessary for the various contractors and other organizations at the site.
- Bidding and contracting. The strategy should conceptually describe the plan
 for bidding and/or contracting the necessary items in the contingency plan. This
 could include a prequalified bidders list or at least tentative identification of
 contractors that can provide appropriate services and an estimate of the
 necessary lead time for procurement.
- **Stop work issues.** The strategy should describe under what conditions the contingency plan could result in a stop work order.

Submodule 7.3 Notes on SAFER During RD/RA

Waste management. If implementation of a contingency plan will result in a secondary waste stream, the requirements of managing the waste stream should be conceptually described in the strategy.
Effects on monitoring plan. The strategy should describe conceptually how implementation of the contingency plan could impact the monitoring system. If deviations occur that change the conceptual site model, impact on the monitoring plan should be identified.
Effects on permits. If a contingency plan requires permits, the strategy should identify the time to obtain specific permits as well as potential roadblocks.

Note B.Monitoring Plan Checklist. SAFER relies on the ability to observe the response of critical parameters of the environmental system to the remedial action being taken. The interpretation and evaluation of the critical parameters identify both when the site restoration is complete and how actual field conditions compare with the expected probable conditions. Careful selection of which parameters to monitor is essential to developing effective decision rules and monitoring systems.

Considerations include the following:

- The parameter values can be estimated. The probable conditions and deviations must be sufficiently characterized such that the environmental response under each condition can be estimated. The success of SAFER depends on estimating in advance the response of the system to the remedial action.
- The parameter values can be measured. Because the parameters will be used
 to compare each probable condition with the environmental response, they must
 be measurable. If a critical parameter cannot itself be directly measured, then
 the measurement of its surrogate will introduce an additional uncertainty factor
 that must be considered.
- A difference in estimated and measured values can be identified. The difference between the estimated and measured responses will be used to determine whether the environmental system is best represented by the probable condition or by a deviation. The ability to determine significant differences (i.e., those indicating a deviation) is critical to the success of SAFER. This is provided through development of a monitoring decision rule.
- **Deviations can be detected in time to implement a contingency plan.** The success of SAFER also depends on the ability to implement contingency plans before further harm can occur to public health or the environment.
- The cause of a deviation can be determined. It is necessary to know what the problem is (i.e., the cause of the difference between expected and measured values) before the appropriate contingency plan can be implemented.

The Note B graphics identify typical parameters that could be observed for different remedial actions for groundwater and soil, respectively.

Submodule 7.3 Notes on SAFER During RD/RA

Example Parameters to	Observe for Grou	ındwater Remed	liation	
		Example Reme	dial Action	
Parameters to Observe ^a	Natural Attenuation	Containmen t	In Situ Treatment	Removal
Regional and local groundwater levels and gradients		•	•	•
Contaminant concentrations in target zone	•		•	•
Treatment parameter concentrations in target zone			•	
Downgradient concentrations	•	•	•	•
Gradient control or removal flow rates		•		•
Chemical concentrations in influent to treatment system				•
Chemical concentrations in effluent from treatment system				•
^a Listing not all-inclusive. Parameters are a func	tion of specific an	olication and site-	specific conditi	ons.

Submodule 7.3 Notes on SAFER During RD/RA

Ex	Example Parameters to Observe for Soil Remediation	Observe for So	oil Remediation			
			Example Remedial Action	Action*		
Parameters to Observe ^b	Flushing by Natural Recharge	Accelerated Flushing	In Situ Bioremediation	Soil Vapor Extraction	Air Sparging	In Situ Stabilization
Concentrations in soil after periods of treatment or natural recharge	•	•	•	•	•	•
Regional and local groundwater levels and gradients		•			•	•
Downgradient groundwater concentrations	•	•	•	•	•	•
Soil vapor concentrations in target zone				•	•	
Pressures/vacuums in target zone				•	•	
Oxygen (DO and O ₂) concentrations in target zone			•		•	
Nutrient concentrations in target zone			•			
Regional soil vapor concentrations	•		•	•	•	
*Other than dig and haul or dig, treat, and haul. For dig and haul response action, the primary concern relates to significant deviations between predicted and actual depth, surface area, or volume of soil to be removed. *Listing not all-inclusive. Parameters are a function of specific application and site-specific conditions.	nd haul. For dig and haul response action, the primary concern or volume of soil to be removed. e a function of specific application and site-specific conditions.	nse action, the pi d. on and site-speci	rimary concern rela fic conditions.	tes to significar	ıt deviations b	etween